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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,260	NASH ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

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Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, and 5-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, and 5-38 are pending.

2. The following new grounds of rejections are necessitated by the amendment filed 11/6/03.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, and 5-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for a method for the production of a microbial adherence inhibitor in the form of IgY for administration to food animals to inhibit the adherence of targeted colony-forming bacteria in the rumen or intestinal tracts of said food animal wherein the colony-forming bacteria are selected from the group consisting of *P. anaerobius, C. sticklandii, C. aminophilium, E. Coli, Listeria, Salmonella* and *Campylobacter* which method comprises inoculating female chickens, in or about to reach their egg laying age, with said colony-forming bacteria; allowing a period of time sufficient to permit the production in the bird of antibody to said targeted immunogen; Harvesting the eggs laid by the birds; Separating the antibody-containing contents of said eggs from the shells and Drying said separated antibody-containing contents of said eggs, said dried entire contents of said eggs when administered to the food animal inhibiting the adherence of the colony-forming bacteria in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming bacteria being assisted by the IgM and IgA immunoglobulin, **does not** reasonably provide enablement for a method for the production of *any* microbial adherence inhibitor for administration to food animal or any living being as set forth in claims 1, 3, and 5-38. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope

of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a method of making microbial adherence inhibitors in the form of chicken egg antibodies IgY that specifically bind to colony forming bacteria selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli serogroup 0157*. The microbial adherence inhibitor produced by the method of inoculating female bird with the specific bacteria such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, and *E coli* serogroup *0157*, harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to inhibit the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

The specification does not teach how to make much less how to use any microbial adherence inhibitor in form of egg antibody that binds to *any* undisclosed colony-forming immunogen because "immunogen" could be peptide, protein, bacteria, virus, or parasite. However, peptide or protein antigen without the specific amino acid sequence has no structure. Further, there is inadequate guidance as to which undisclosed colony forming immunogen such as bacteria, parasite, or virus that when colonized the rumen or intestinal tracts of which animal would cause food wasting and reduce the growth of the animal. Until the colony-forming immunogen such as bacteria, virus, or parasite that wasting dietary protein has been identified, the microbial adherence inhibitor in form of egg antibody to that binds to the undisclosed colony-forming immunogen cannot be made. Given the indefinite number of colony-forming immunogen, there is insufficient guidance as to the binding specificity of the microbial adherence inhibitor.

Stryer *et al*, of record, teach that a protein (immunogen) is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformational of the protein (See enclosed appropriate pages). Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment

derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al*, of record, teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Given the indefinite number of undisclosed colony-forming immunogen, it is unpredictable which undisclosed microbial inhibitor in the form of chicken antibody IgY including IgA and IgM in the albumin would bind specifically to said undisclosed colony-forming immunogen, in turn, would be useful for inhibiting the adherence of any protein wasting immunogen (bacteria) in the food animals or living being. Given the indefinite number of undisclosed microbial adherence inhibitor, there is no *in vivo* working example demonstrating that the claimed microbial adherence inhibitor is effective for inhibiting the adherence of all colony-forming immunogen (bacteria, parasites, virus, etc) in the rumen or intestinal tracts of food animal.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

5. Claims 1, 3, and 5-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a method for the production of *any* microbial adherence inhibitor for administration to food animal or any living being as set forth in claims 1, 3, and 5-38 to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

The specification discloses only a method of making microbial adherence inhibitors in the form of chicken egg antibodies IgY that specifically bind to colony forming bacteria selected from the group consisting of *P. anaerobius, C. Sticklandii, C. aminophilum, E coli serogroup 0157.* The microbial adherence inhibitor produced by the method of inoculating female bird with the specific bacteria such as *P. anaerobius, C. Sticklandii, C. aminophilum,* and *E coli* serogroup *0157,* harvesting the eggs, mixing and pasteurizing the whole egg prior to mixing with the animal feed or water with said egg antibody to inhibit the adherence of said specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

Other the specific colony-forming bacteria *P. anaerobius, C. sticklandii, C. aminophilium, E coli, Listeria, Salmonella* for a method of producing microbial adherence inhibitor in the form of IgY that binds specifically to said colony-forming bacteria to inhibit the adherence of said bacteria in the rumen or digestive track of food animal, there is inadequate written description about the colony-forming immunogen because "immunogen" without the specific amino acid sequence, or biochemical properties has no structure. Further, there is inadequate written description about which undisclosed colony forming immunogen such as bacteria, parasite, and virus that when colonized the rumen or intestinal tracts of which animal would cause food wasting and reduce the growth of the animal. Until the "colony-forming immunogen" has been identified, the method of producing the microbial adherence inhibitor in form of egg antibody that binds to the undisclosed colony-forming immunogen cannot be made. Given the infinite number of undisclosed colony-forming immunogen, the method of producing said undisclosed colony forming immunogen has not been adequately described, and the binding specificity of microbial adherence inhibitor in the form of IgY including IgA and IgM is also not adequately described.

Since the specification discloses only a microbial inhibitor produced by inoculating with the following six colony-forming immunogens such as bacteria selected from the group consisting of *P. anaerobius, C. Sticklandii, C. aminophilum, E coli* serogroup 0157: H7, *Salmonella,* and *Campylobacter*, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the method of producing the genus of colony-forming immunogens that inhibit the adherence of a colony forming immunogen in the digestive track of *any* living being. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

6. Claims 5, and 32-38 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The "living being" in Claims 5, 32, 34, 36, and 38 represents a departure from the specification and the claims as originally filed. The passages pointed out by applicant in the amendment filed 11/6/03 do not provide a clear support for the said phrase.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1, and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "protein wasting immunogen" in claim 1 has no antecedent in the preamble. The preamble of claim 1 recites "targeted colony-forming immunogen".

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3, 5, 8, 11, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) or Yokoyama *et al* (Infection and Immunity 60(3): 998-1007, March 1992; PTO 892) each in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), and Trinchieri *et al* (Urol Res 18(5): 305-8, 1990; PTO 892).

The '895 patent teaches method of producing a microbial adherence inhibitor such as a yolk antibody that inhibits the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial adherence inhibitor is produced by inoculating an egg laying hen in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

Yokoyama *et al* teach a method of producing a microbial adherence inhibitor such as IgY for administration to food animal such as piglets to inhibit the adherence of a targeted colony forming immunogen such as E coli in the intestinal tracts of reference animal (See abstract, in particular). The reference method comprises inoculating the hen in or about to reach their egg laying age with the reference colony forming immunogen such as E coli (See page 999, Immunization with fimbrial vaccine, in particular), harvesting the eggs lay by the chickens and

separating the IgY from the yolk (See page 999, column 2, Separation of antibodies from chicken egg yolk, in particular), drying the separated IgY (See page 1000, column 2, Production of antibody powders by spray drying, in particular) and when administering yolk antibodies to the living being such as neonatal piglets, the yolk antibodies inhibit the adherence of the colony forming immunogen E coli in the digestive tract.

The claimed invention in claims 1, and 5 differs from the teachings of the references only that the method wherein the entire contents of the harvested eggs which include IgY in the yolks, and IgM and IgA in the albumin of the eggs are dried.

The claimed invention in claim 3 differs from the teachings of the references only that the method wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii*, and *C. aminophilium*.

The claimed invention in claim 8 differs from the teachings of the references only that the method wherein the entire contents of the harvested eggs which include IgY in the yolks, and IgM and IgA in the albumin of the eggs are dried and the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *P. anaerobius*.

The claimed invention in claim 11 differs from the teachings of the references only that the method wherein the entire contents of the harvested eggs which include IgY in the yolks, and IgM and IgA in the albumin of the eggs are dried and the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. sticklandii*.

The claimed invention in claim 14 differs from the teachings of the reference only that the method wherein the entire contents of the harvested eggs which include IgY in the yolks, and IgM and IgA in the albumin of the eggs are dried and the microbial adherence inhibitor wherein the colony-forming immunogen is from the class consisting of *C. aminophilium*.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and/or mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg (the entire contents) than mere purified sprayed-dried antibodies, i.e. IgY fraction (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases only the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Trinchieri *et al* teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent or Yokoyama et al for the *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium* that are responsible for ruminal amino acid degradation as taught by Krause *et al* for a method of producing egg antibody IgY as taught by the '895 patent and Yokoyama et al. It would have been obvious to one ordinary skill in the art at the time the invention was made to dry the separated entire contents whole egg (white and yolk) antibody without first isolating the antibodies from the yolk as taught by the '489 patent since (IgY) is primary the immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin as taught by Kaspers *et al.* Trinchieri *et al* teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular). From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '489 patent teaches that antibodies form the spay-dried whole egg are more resistant to degradation by gastric acidity than the purified (IgY yolk fraction) sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). Yokoyama et al teach when administered yolk antibodies to *E coli* to the living being such as neonatal piglets, the yolk antibodies inhibit the adherence of the colony forming immunogen E coli in the digest tract. Trinchieri et al teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular). Krause *et al* teach that *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Although monensin as a ruminant feed additive can decrease only the number of *P.*

anaerobius and *C. sticklandii*, monesin does not decrease the number of *C. aminophilium* in livestock.

Applicants' arguments filed 11/6/03 have been fully considered but are not found persuasive.

Applicants' position is that (1) claims 2 and 4 have been canceled. (2) claims 1, 5 and 17 define a method of a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestine tracts of live beings and the method uses the entire contents of eggs having the IgY immunoglobulins and IgA and IgM immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein by the presence of protein-wasting immunogens in the intestinal tracts of the animals. (3) Tokoro ('895) discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). Tokoro is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in Tokoro of an lgY immunoglobulin that binds to a colony-forming immunogen. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. Tokoro does not provide a teaching of a method for the production of a microbial adherence inhibitor for promoting the growth of food animals by binding lgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilium* to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

However, the '489 patent teaches that whole egg (white and yolk) antibody can be dried and/or mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg (the entire contents) than mere purified sprayed-dried antibodies, i.e. IgY fraction (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). Trinchieri et al teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular).

In contrast to applicants' assertion that there is no disclosure in Tokoro of an IgY immunoglobulin that binds to a colony-forming immunogen, the '895 patent teaches a method of making IgY immunoglobulin to colony-forming immunogen such as E coli (See column 5, lines 29-30, in particular). The reference egg yolk inherently contains the IgY immunoglobulins while the reference albumin inherently contains the IgM and IgA class of immunoglobulins that help IgY immunoglobulin to inhibit the adherence of E coli to the rumen or intestinal tract.

Yokoyama *et al* teach a method of producing a microbial adherence inhibitor such as IgY for administration to food animal such as piglets to inhibit the adherence of a targeted colony forming immunogen such as E coli in the intestinal tracts of reference animal (See abstract, in particular). The reference method comprises inoculating the hen in or about to reach their egg laying age with the reference colony forming immunogen such as E coli (See page 999, Immunization with fimbrial vaccine, in particular), harvesting the eggs lay by the chickens and separating the IgY from the yolk (See page 999, column 2, Separation of antibodies from chicken egg yolk, in particular), drying the separated IgY (See page 1000, column 2, Production of antibody powders by spray drying, in particular) and when administering yolk antibodies to the living being such as neonatal piglets, the yolk antibodies inhibit the adherence of the colony forming immunogen E coli in the digestive tract.

The claimed invention differs from the teachings of the reference only that the method wherein the entire contents of the harvested eggs which include IgY in the yolks, and IgM and IgA in the albumin of the eggs are dried and the colony-forming immunogen is from the class consisting of P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilium* to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and/or mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg (the entire contents) than mere purified sprayed-dried antibodies, i.e. IgY fraction (see column 2, lines 35-39, in particular).

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases only the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Trinchieri *et al* teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent or Yokoyama et al for the *Peptostreptococcus anaerobius, Closteridium sticklandii, and/or Clostridium aminophilium* that are responsible for ruminal amino acid degradation as taught by Krause *et al* for a method of producing egg antibody IgY as taught by the '895 patent and Yokoyama et al. It would have been obvious to one ordinary skill in the art at the time the invention was made to dry the separated entire contents whole egg (white and yolk) antibody without first isolating the antibodies from the yolk as taught by the '489 patent since (IgY) is primary the immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin as taught by Kaspers *et al.* Trinchieri *et al* teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular). From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '489 patent teaches that antibodies form the spay-dried whole egg are more resistant to degradation by gastric acidity than the purified (IgY yolk fraction) sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular). Yokoyama et al teach when administered yolk antibodies to *E coli* to the living being such as neonatal piglets, the yolk antibodies inhibit the adherence of the colony forming immunogen E coli in the digest tract. Trinchieri et al teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular). Krause *et al* teach that *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Although monensin as a ruminant feed additive can decrease only the number of *P.*

anaerobius and *C. sticklandii*, monesin does not decrease the number of *C. aminophilium* in livestock.

11. Claims 5, 20, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) or Yokoyama *et al* (Infection and Immunity 60(3): 998-1007, March 1992; PTO 892) each in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), and Trinchieri *et al* (Urol Res 18(5): 305-8, 1990; PTO 892) as applied to claims 1, 3, 5, 8, 11, 14, and 17 and further in view of US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892).

The combined teachings of the '895 patent, Yokoyama et al, Kaspers et al, the '489 Krause *et al,* Trinchieri *et al* have been discussed supra.

The claimed invention in claims 5, 20, 23 and 23 differs from the combined teachings of the references only that the method wherein the colony-forming immunogen is *Listeria, Salmonella* or *Campylolacter*.

The '018 patent teaches a method of making IgY antibody to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as *Listeria, Salmonella and Campylobacter*, wherein the reference immunogens are colony-forming bacteria that are known to cause food borne illness in humans by decreasing an animal's ability to absorb nutrient, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference IgY microbial adherence inhibitor inhibits the adhesion of

Salamonella to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the *E coli* as taught by the '895 patent or Yokoyama for the *Listeria, Salmonella* and/or *Campylobacter* as taught by the '018 patent or the *Salamonella* as taught by Sugita-Konishi *et al* for making a microbial adherence inhibitor in the form of IgY, IgA and IgM antibody as taught by Kaspers *et al* to *Listeria, Salmonella* and/or *Campylobacter and* the '018 patent, Sugita-Konishi *et al* or Yokoyama *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Sugita-Konishi *et al* teach that egg antibody to *Salamonella* inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). The '018 patent teaches that IgY antibody that binds specifically to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular) is useful for a method of passive immunity (See abstract, in particular). The '489 patent teaches that whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular) and such antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg as compared to purified sprayed-dried antibodies (see column 2, lines 35-39, in particular). Kaspers *et al* teach IgG (IgY) is the primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

12. Claims 6, 7, 9-10, 12-13, 15-16, 18-19, and 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) or Yokoyama *et al* (Infection and Immunity 60(3): 998-1007, March 1992; PTO 892) each in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), and Trinchieri *et al* (Urol Res 18(5): 305-8, 1990; PTO 892) as applied to claims 1, 3, 5, 8, 11, 14, and 17 and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent, Yokoyama et al, Kaspers et al, the '489 Krause *et al,* Trinchieri *et al* have been discussed supra.

The claimed invention in claims 6, and 29 differs from the combined teachings of the references only that the method wherein coating said dry feed carrier material with the separated contents of the harvested eggs, said dry food carrier material coated with the entire contents of the said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony forming immunogen being assisted by the IgM and IgA immunogloblulins.

The claimed invention in claim 7, 9, 12, 15, 18, differs from the combined teachings of the references only that the method including a dry carrier material, said drying the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

The claimed invention in claims 10, 13, 16, 19, 30, 33, 35, 37 differs from the combined teachings of the references only that the method including a dry carrier material, wherein the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claims 31 differs from the combined teachings of the references only that the method wherein the target forming immunogen is from the class consisting of *P anaerobius, C sticklandii, and C aminophilium.*

The claimed invention in claim 32 differs from the combined teachings of the references only that the method wherein coating said dry feed carrier material with the separated contents of the harvested eggs, said dry food carrier material coated with the entire contents of the said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony forming immunogen being assisted by the IgM and IgA immunogloblulins and wherein the immunogen is P antigen from *P anaerobius*.

The claimed invention in claim 33 differs from the combined teachings of the references only that the method wherein coating said dry feed carrier material with the separated contents of the harvested eggs, said dry food carrier material coated with the entire contents of the said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen,

said binding of the IgY immunoglobulins to the colony forming immunogen being assisted by the IgM and IgA immunogloblulins and wherein the immunogen is CS antigen from *C sticklanddi.*

The claimed invention in claim 36 differs from the combined teachings of the references only that the method wherein coating said dry feed carrier material with the separated contents of the harvested eggs, said dry food carrier material coated with the entire contents of the said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony forming immunogen being assisted by the IgM and IgA immunogloblulins and wherein the immunogen is CA antigen from *C aminiphilium.*

The claimed invention in claim 38 differs from the combined teachings of the references only that the method wherein coating said dry feed carrier material with the separated contents of the harvested eggs, said dry food carrier material coated with the entire contents of the said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony forming immunogen being assisted by the IgM and IgA immunogloblulins and wherein the immunogen is *E coli.*

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches high performance palatable horse feed carrier such as soybean hulls, rice hulls cottonseed hulls provides the fibrous material and cereal grain such as corn and distilled dried grains provides the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made by coating the dry feed carrier material such as soybean hulls, rice hulls and cottonseed hulls as taught by the '878 patent and/or the '867 patent with the immunoglobulins from the entire contents of said eggs to *E coli, Peptostreptococcus anaerobius, Closteridium*

sticklandii, or *Clostridium aminophilium* as taught by the '895 patent, Yokoyama et al, Kaspers et al, the '489 Krause *et al,* Trinchieri *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '878 patent teaches that hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular). The recitation of coating said dry feed carrier material with the separated contents of the harvested eggs is an obvious variation of teachings of the'489 patent since whole egg (white and yolk) antibody can be dried and/or mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg (the entire contents) than mere purified sprayed-dried antibodies, i.e. IgY fraction (see column 2, lines 35-39, in particular).

13. Claims 20-28 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) or Yokoyama *et al* (Infection and Immunity 60(3): 998-1007, March 1992; PTO 892) each in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, June 1996; PTO 892), US Pat No 5,741,489 (of record, April 1998; PTO 1449), Trinchieri *et al* (Urol Res 18(5): 305-8, 1990; PTO 892), US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892), US Pat No 4,748,018 (of record, May 31, 1988; PTO 1449), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892).

The '895 patent teaches method of producing a microbial adherence inhibitor such as a yolk antibody that inhibits the targeted colony-forming bacteria (immunogen) such as *E coli* from adhering to the intestinal track of a living being such as livestock since the reference antibody is able to prevent diarrhea that results in wasting of dietary protein. The reference microbial

adherence inhibitor is produced by inoculating an egg laying hen in their egg laying age with the reference immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks after inoculation sufficient to permit the production of bird antibody that binds to the targeted immunogen such as *E Coli* (See column 5, lines 47-60, column 6, 10-18, in particular), harvesting the egg laid by the hen (See column 6, line 1, in particular), separating the yolk and albumen (the entire content of the egg) (See column 6, lines 19-20, in particular), drying the separated egg antibody by spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent further teaches various microbial adherence inhibitors such as egg antibodies produced by the method of inoculating the female bird with immunogens such as K88, K99 and 987P from *E coli* of interest and egg antibody is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

Yokoyama *et al* teach a method of producing a microbial adherence inhibitor such as IgY for administration to food animal such as piglets to inhibit the adherence of a targeted colony forming immunogen such as E coli in the intestinal tracts of reference animal (See abstract, in particular). The reference method comprises inoculating the hen in or about to reach their egg laying age with the reference colony forming immunogen such as E coli (See page 999, Immunization with fimbrial vaccine, in particular), harvesting the eggs lay by the chickens and separating the IgY from the yolk (See page 999, column 2, Separation of antibodies from chicken egg yolk, in particular), drying the separated IgY (See page 1000, column 2, Production of antibody powders by spray drying, in particular) and when administering yolk antibodies to the living being such as neonatal piglets, the yolk antibodies inhibit the adherence of the colony forming immunogen E coli in the digestive tract.

The claimed invention in claim 21, 24, and 27 differs from the combined teachings of the references only that the method including a dry carrier material, said drying the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

The claimed invention in claims 22, 25, and 28 differs from the combined teachings of the references only that the method including a dry carrier material, said drying the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs wherein the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 38 differs from the combined teachings of the references only that the method wherein coating said dry feed carrier material with the separated contents of the harvested eggs, said dry food carrier material coated with the entire contents of the said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding to the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony forming immunogen being assisted by the IgM and IgA immunogloblulins and wherein the immunogen is *Listeria, Salmonella* and *Campylobacter.*

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '489 patent teaches that whole egg (white and yolk) antibody can be dried and/or mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg (the entire contents) than mere purified sprayed-dried antibodies, i.e. IgY fraction (see column 2, lines 35-39, in particular).

Trinchieri *et al* teach that the attachment of *E coli* to human uroepithelial cells is inhibited by high level of the IgA (Abstract, in particular).

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches high performance palatable horse feed carrier such as soybean hulls, rice hulls cottonseed hulls provides the fibrous material and cereal grain such as corn and distilled dried grains provides the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches

soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

The '018 patent teaches a method of making IgY antibody to colony forming immunogen or combination of immunogen (antigen) such as *E coli, Listeria, Salmonella* and *Campylobacter* (See column 5, lines 1-30, column 6, line 22-25, in particular). The reference antibody is produced by the method of inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as *Listeria, Salmonella and Campylobacter*, wherein the reference immunogens are colony-forming bacteria that are known to cause food borne illness in humans by decreasing an animal's ability to absorb nutrient, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody is useful for a method of passive immunity (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference IgY microbial adherence inhibitor inhibits the adhesion of *Salamonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made by coating the dry feed carrier material such as soybean hulls, rice hulls and cottonseed hulls as taught by the '878 patent and/or the '867 patent with the immunoglobulins from the entire contents of said eggs to *Listeria, Salmonella* and *Campylobacter* as taught by the '895 patent, Yokoyama et al, Kaspers et al, the '489 Trinchieri *et al,* '018 patent, Sugita-Konishi *et al, and* Yokoyama *et al.* From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated with an expectation of success to do this because the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in

subject animal (See column 9, lines 37-46). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular). The method of coating dry food carrier is an obvious variation of the teachings of the'489 patent since whole egg (white and yolk) antibody can be dried and/or mixed with feed without first isolating the antibodies from the yolk (see column 2, lines 7-8, column 5, line 52-56, in particular). The '489 patent further teaches that antibodies have been reported to be more resistant to degradation by gastric acidity when are contained in the spay-dried whole egg (the entire contents) than mere purified sprayed-dried antibodies, i.e. IgY fraction (see column 2, lines 35-39, in particular). Further, the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier such as food pellets.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 3, and 5-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-16, 19-24, 27-32 of copending Application No. 09/616,843. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issuance of a patent to the method of making bird antibody to any colony forming immunogen genus (claims 1, 6-7, and 29-30) of instant application would include the method of making bird antibody to the specific immunogen such as *P anaerobius, C. sticklandii*, and *C aminophilium* (species) (claims 14-16, 19-24, 27-32 of copending Application No. 09/616,843). The method of inhibiting the colony forming bacteria from adhering to the digestive tract and thereby reducing the protein wasting and promoting the growth of the food animal is an inherent properties of the immunoglobulins.

Claims 3, 8-16, and 31-37 of instant application are drawn to a method of making microbial inhibitor in the form of bird antibody to the specific immunogen such as *P anaerobius, C. sticklandii*, and *C aminophilium* which are nearly the same method as claims 14-16, 19-24, 27-32 of copending Application No. 09/616,843 which drawn to a method of promoting the growth of the animal by decreasing the waste of dietary protein by making bird antibody that binds to *P anaerobius, C. sticklandii*, and *C aminophilium*. These method steps are obvious variation, however, the binding specificity of the IgY to the specific immunogen is the same. The method of inhibiting the colony forming bacteria from adhering to the digestive tract and thereby reducing the protein wasting and promoting the growth of the food animal is the inherent properties of the IgY in the yolk, the IgA and IgM in the albumin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 5, and 17-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/039,977.

The method of making microbial adherence inhibitor to the same immunogen such as *E coli, Listeria, Salmonella* and *Campylobacter* in instant application and copending application 10/039,977 would result in the same antibody. The method of inhibiting the colony forming bacteria from adhering to the digestive tract and thereby reducing the protein wasting and promoting the growth of the food animal is the inherent properties of the immunoglobulins.

The antibody containing contents of the eggs in claims 1-18 of copending Application No. 10/039,977 would include IgY from the yolk and the IgA and IgM from the albumin to E coli, Listeria, Salmonella and Campylobacter of instant 5, and 17-28.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

20. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
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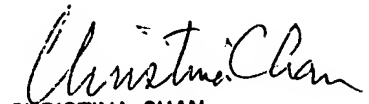
Technology Center 1600
February 9, 2004



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